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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,619	11/21/2003	Ryo Goitsuka	2003_1609	3668

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WASHINGTON, DC 20006-1021

EXAMINER

ROOKE, AGNES BEATA

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/717,619

Applicant(s)

GOITSUKA, RYO

Examiner

Agnes B. Rooke

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-10 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1, drawn to a protein of SEQ ID NO:2, classified in class 530, subclass 350.
- II. Claim 2, drawn to a protein of SEQ ID NO:4, classified in class 530, subclass 350.
- III. Claims 3, 5, 7, drawn to a polynucleotide of SEQ ID NO:1, classified in class 435, subclass 69.1.
- IV. Claims 4, 6, 8, drawn to a polynucleotide of SEQ ID NO:3, classified in class 435, subclass 69.1.
- V. Claim 9, drawn to an antibody against a protein of SEQ ID NO:2, classified in class 530, subclass 387.1.
- VI. Claim 10, drawn to an antibody against a protein of SEQ ID NO:4, classified in class 530, subclass 387.1.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acid of Invention III is related to a polypeptide of Invention I by virtue of encoding the same. Although nucleic acid and polypeptide are related, since nucleic acid encodes the specifically claimed polypeptide, they are distinct inventions because the polypeptide product can be made by another materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the

nucleic acid may be used for processes other than the production of the polypeptide, such as hybridization assay.

The nucleic acid of Invention IV is related to a polypeptide of Invention II by virtue of encoding the same. Although nucleic acid and polypeptide are related, since nucleic acid encodes the specifically claimed polypeptide, they are distinct inventions because the polypeptide product can be made by another materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the nucleic acid may be used for processes other than the production of the polypeptide, such as hybridization assay.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the Inventions I and II are distinct because each of them has a distinct amino acid sequence that encodes a distinct protein of a different structure.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the Inventions III and IV are distinct because each of them has a distinct nucleic acid sequence that encodes a distinct protein of a different structure.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the polypeptide of Invention I and the antibody of Invention V are structurally distinct molecules, and any relationship between a polypeptide of Invention I and antibody of Invention V is dependent upon the correlation between the scope of the polypeptides that the antibody binds to and the scope of the antibodies that would be generated upon immunization with the peptide. Further, a separate search would be necessary to search the polypeptide and the antibody.

Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the polypeptide of Invention II and the antibody of Invention VI are structurally distinct molecules, and any relationship between a polypeptide of Invention II and antibody of Invention VI is dependent upon the correlation between the scope of the polypeptides that the antibody binds to and the scope of the antibodies that would be generated upon immunization with the peptide. Further, a separate search would be necessary to search the polypeptide and the antibody.

Inventions III/IV and V/VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Inventions III and IV refer to polynucleotides and Inventions V and VI refer to antibodies. Polynucleotides and antibodies have a completely distinct structure and function, and are not capable of being used together, because the polynucleotide of Invention III will not encode an antibody of Invention VI, and an antibody of Invention V cannot be encoded by a polynucleotide of Invention IV. Therefore, the inventions are patently distinct.

Because the inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for the examination purposes as indicated is proper.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply, where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the Invention to be examined even though the requirement be traversed (37 CFR 1.143).

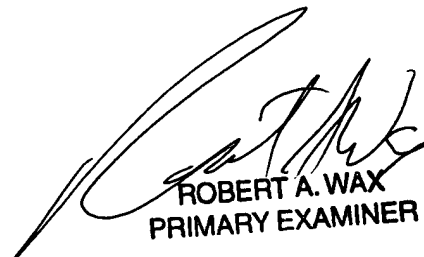
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

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supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

AR



ROBERT A. WAX
PRIMARY EXAMINER